



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/524,196

02/23/2006

Nils Holmstrom

P05,0038

4110

26574

7590

08/25/2008

SCHIFF HARDIN, LLP
PATENT DEPARTMENT
6600 SEARS TOWER
CHICAGO, IL 60606-6473

EXAMINER

DANEGA, RENEE A

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

08/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,196	Applicant(s) HOLMSTROM ET AL.	
	Examiner RENEE DANEGA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-32 is/are pending in the application.
- 4a) Of the above claim(s) 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/10/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 18-31, drawn to a congestive heart failure monitor.

Group II, claim(s) 32, drawn to a multi-site heart stimulator.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group II has a stimulation unit adapted to interact with cardiac tissue to electrically stimulate cardiac tissue with pacing pulses not found in Group I.

3. During a telephone conversation with Attorney Steven Noll on 8/19/08 a provisional election was made without traverse to prosecute the invention of Group I, claims 18-31. Affirmation of this election must be made by applicant in replying to this Office action. Claim 32 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 18, and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakels et al. (US 6223079) in view of Geddes ("Use of Impedance Ratio of Stroke Volume of a Valveless Pouch Used as a Cardiac-Assist Device").

- Regarding claim 18, Bakels teaches a congestive heart failure monitor comprising an impedance-measuring unit having two electrodes (57) (58) adapted to interact with a patient to measure an impedance representative of a change in a volume of the left atrium of the heart of the patient; and an analyzing unit (40) supplied with a signal representing said impedance and detecting congestive heart failure (Figures 2A, 2B, 8B) (column 2, lines 55-66). Bakels doesn't expressly teach the analyzing unit to include a quotient determining unit to determine a quotient between minimum and maximum impedance during a cardiac cycle. However, Geddes teaches using an impedance quotient of minimum and maximum impedances in order to determine stroke volume (abstract) (page 3, column 1). It would have been obvious in view of Geddes to provide a quotient determining

unit as part of Bakel's analyzing unit in order to determine the stroke volume of a patient.

- Regarding claims 26 and 27, Bakels teaches electrodes able to be implanted in the right and left atria and ventricles (53) (54) (57) (58) (Figure 2B).
- Regarding claim 28, Bakels teaches a monitor comprising a housing adapted for implantation in the patient containing the impedance measuring unit, the analyzing unit, and wherein a first of the electrodes is adapted for implantation in the left atrium (57) and a second of the electrodes is formed by an exterior of the housing (32A) (Figures 2A, 2B) (Column 6, lines 4-29).
- Regarding claim 29, Bakels teaches the electrodes are adapted for implantation respective in the left atrium and ventricle proceeding in a coronary vein (column 5, lines 45-55).

3. Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakels and Geddes as applied to claim 18 above, and further in view of Pitts Crick et al. (US 6104949).

- Regarding claims 19, 21- 22, and 24, Bakels and Geddes don't expressly teach the analysis unit to include an averaging unit capable of forming a floating average impedance value. However, Pitts Crick teaches an averaging unit for performing a floating average of impedances in order to create a baseline for determining congestive heart failure (column 5, lines

23-57). It would have been obvious in view of Pitts Crick to form an average in order to account for postural changes in determining congestive heart failure.

- Regarding claims 20 and 23, Bakels teaches the analysis unit to comprise a comparator capable of comparing an average with a predetermined value (column 10, lines 35-43).
- Regarding claim 25, Bakels and Geddes don't teach averaging units and comparators for quotient and impedance values for first and second results. Bakels does teach that congestive heart failure can be identified by impedance measurements of blood volume and valve closure (column 6, lines 63-66). However, Pitts Crick teaches two comparators in the determination of congestive heart failure (5-6) (5-8). It would have been obvious in view of Pitts Crick to provide multiple comparators to allow for more than one indicator of congestive heart failure to be identified. It further would have been obvious in view of Bakels to provide multiple averaging units in order to permit multiple data to be processed in the identification of congestive heart failure

4. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bakels and Geddes as applied to claim 18 above, and further in view of Bernstein et al. (US 20020193689).

- Regarding claim 30, Bakels doesn't teach the measuring circuit to be formed by a synchronous demodulator. However, Bernstein teaches a

synchronous demodulator (40) able to extract real and imaginary impedance in order to extract impedance information from a voltage measured across a body part [0061] (Figure1). It would have been obvious in view of Bernstein to provide a synchronous demodulator in order to extract impedance information from a voltage measured across a body part.

5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bakels and Geddes as applied to claim 18 above, and further in view of Feldman (US 5788643).

- Regarding claim 31, Bakels doesn't teach the monitor wherein the impedance measuring unit determines a phase angle of the impedance wherein the analyzing unit analyzes the phase angle to detect congestive heart failure. However, Feldman teaches a measuring unit determining phase angle of impedance and analyzing it in the determination of chronic congestive heart failure (Figure 2). It would have been obvious in view of Feldman to provide phase angle determination capabilities in order to determine whether to initiate intervention in cases of chronic congestive heart failure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENEE DANEGA whose telephone number is

Art Unit: 3736

(571)270-3639. The examiner can normally be reached on Monday through Thursday 7:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736